

REMARKS

In the Office Action mailed September 15, 2009, the Examiner took the following actions:

(a) rejected claims 69-74, 83-87, 93, 95, 98, and 99 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,254,534 to Butler et al. ("Butler") in view of U.S. Patent No. 5,848,992 to Hart et al. ("Hart"); and

(b) rejected claims 69, 75-82, 88-90, 94, 96, 97, and 100 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,254,533 to Fadem et al. ("Fadem") in view of Hart.

By this reply, Applicant amends claim 69; cancels claims 75-100; and adds new claims 101-112. Accordingly, claims 69-74 and 101-112 are pending in this application. No new matter has been introduced by this reply.

I. Rejection under 35 U.S.C. § 103(a) based on Butler and Hart

On page 2 of the Office Action, claims 69-74, 83-87, 93, 95, 98, and 99 were rejected under 35 U.S.C. § 103(a) as unpatentable over Butler in view of Hart. Of claims 69-74, 83-87, 93, 95, 98, and 99, claims 69 and 83 are independent. Claim 69 has been amended, and claim 83 has been cancelled. Claim 69 now recites, *inter alia*, "at least three accessways to facilitate sealed access through the retracted opening . . . a sum of the diameters of at least two of the accessways being greater than a radius of the sealing member." Support for this recitation can be found at least in FIGS. 32-44 of Applicant's drawings (see, e.g., FIG. 36). Applicant submits that neither Butler nor Hart teaches these aspects of claim 69, and thus, the amendment to claim 69 overcomes the rejection under 35 U.S.C. § 103(a) based on Butler and Hart.

Butler teaches a wound retractor 150 for retracting a wound opening 103 that includes an inner O-ring 105, a sleeve 106, and outer and inner ring parts 110, 111.

See Butler at column 5, lines 49-52; column 6, lines 36-40, and 46-49; and FIG. 25.

Butler also teaches a hand access device 175 including a single accessway, mounted on inner ring part 110. See id. at column 6, lines 56-61; and FIG 25. Butler fails to teach multiple accessways (a deficiency acknowledged by the Examiner on page 3 of the Office Action), and thus, Butler fails to disclose or suggest the “at least three accessways” recited in amended independent claim 69.

Hart teaches hollow stems 18 attached to a base 14, as shown in FIG. 4. See Hart at column 7, lines 49-52 and 56-60. Page 3 of the Office Action asserts that it would have been obvious to construct the device in Butler with hollow stems 18 of Hart. However, Hart teaches that “hollow stem 18 is centered over the opening 28,” and that, for a plurality of hollow stems 18, “flexible base 14 may also be used to support various sizes of openings 28 to be covered by the hollow stems 18.” Hart, column 6, lines 45 and 46; and column 7, lines 57-61. Thus, Hart teaches that one hollow stem 18 facilitates access through one opening 28, while another hollow stem 18 facilitates access through another opening, i.e., each hollow stem 18 facilitates access through its own corresponding opening 28. This is not unlike Butler, which teaches a single opening (through hand access device 175) for facilitating access through a single wound opening 103 (see FIGS. 24 and 25 of Butler). Therefore, Hart fails to remedy the deficiencies of Butler in that Hart also fails to disclose or suggest, “at least three accessways to facilitate sealed access through the retracted opening,” as recited in amended independent claim 69.

Further, Applicant submits that the combination of Butler and Hart fails to consider the claimed invention as a whole (see M.P.E.P. § 2141.02), in that neither

Butler nor Hart addresses multiple accessways through a retracted opening. For at least this reason, claim 69 is allowable over Butler and Hart. Applicant respectfully cautions against the use of improper hindsight in rejecting the claims of this application. For example, Applicant submits that substantial modification of a secondary reference to reject the claims may evidence the improper use of hindsight reasoning.

Furthermore, Hart does not teach that a sum of the diameters of at least two of hollow stems 18 is greater than a radius of hand access device 175 of Butler. This dimensional relationship between the diameters and the radius prevents a sealing member from having an excessively large size, and is clearly missing from Hart. Therefore, Hart fails to remedy the deficiencies of Butler in that Hart also fails to disclose or suggest, “a sum of the diameters of at least two of the accessways being greater than a radius of the sealing member,” as recited in amended independent claim 69.

The sum of the diameters of at least two of the accessways being greater than a radius of the sealing member, described in amended independent claim 69, provides the surgical device with advantages that are not disclosed or recognized in Butler or Hart. For example, in the present application, making the sum of the diameters of accessways 136 and 137, shown in FIG. 36, greater than the radius of a sealing member 132, provides a sealing member 132 and accessways 136 and 137 that are sized in relation to one another to both accommodate the size of the instruments that travels through the passageways, and reduce the size of incision required for the surgical device. Large incisions are undesirable because they are more traumatic, take longer to heal, and increase the chances for scarring.

For at least the above-outlined reasons, Applicant submits that the amendment to claim 69 overcomes the rejection under 35 U.S.C. § 103(a) based on Butler and Hart. Therefore, claim 69 is allowable over Butler and Hart. Claims 70-74 depend from amended independent claim 69 and are therefore allowable for at least the same reasons that claim 69 is allowable.

II. Rejection under 35 U.S.C. § 103(a) based on Fadem and Hart

On page 4 of the Office Action, claims 69, 75-82, 88-90, 94, 96, 97, and 100 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Fadem in view of Hart. Of claims 69, 75-82, 88-90, 94, 96, 97, and 100, claims 69, 75, and 88 are independent. Claim 69 has been amended, and claims 75 and 88 have been cancelled. Claim 69 now recites, *inter alia*, “at least three accessways to facilitate sealed access through the retracted opening . . . a sum of the diameters of at least two of the accessways being greater than a radius of the sealing member.” Applicant submits that neither Fadem nor Hart teaches these aspects of claim 69, and thus, the amendment to claim 69 overcomes the rejection under 35 U.S.C. § 103(a) based on Fadem and Hart.

Fadem teaches a protractor sleeve 10 coupled to a lower O-ring 14 and an upper O-ring 18, wherein rolling protractor sleeve 10 about upper O-ring 18 brings the sleeve into tight engagement with the sides of a wound incision. See Fadem at column 4, lines 46-53; and FIGS. 1, 2, 3B, and 4. Fadem also teaches inclusion of a cover or dome 108 to provide containment, pressure, security, and cleanliness for a surgical site. See id. at column 6, lines 8-11; and FIG. 4. Fadem also teaches a sealable instrument opening 114 in dome 108. See id. at column 6, lines 13-15; and FIG. 4. Fadem fails to teach multiple accessways (a deficiency acknowledged by the Examiner on page 4 of

the Office Action), and thus, Fadem fails to disclose or suggest “at least three accessways,” as recited in amended independent claim 69.

Hart teaches hollow stems 18 attached to base 14 (shown in FIG. 4). See Hart at column 7, lines 49-52 and 56-60. Page 5 of the Office Action asserts that it would have been obvious to construct the device in Fadem with hollow stems 18 of Hart. However, Hart teaches that “hollow stem 18 is centered over the opening 28,” and that, for a plurality of hollow stems 18, “flexible base 14 may also be used to support various sizes of openings 28 to be covered by the hollow stems 18.” Hart, column 6, lines 45 and 46; and column 7, lines 57-61. In other words, Hart teaches that one hollow stem 18 facilitates access through one opening 28, and that for multiple hollow stems 18, each would facilitate access through its own corresponding opening 28. This is not unlike Fadem, which teaches a single sealable instrument opening 114 (see FIG. 4) for facilitating access through a single wound incision. Therefore, Hart fails to remedy the deficiencies of Fadem in that Hart also fails to disclose or suggest, “at least three accessways to facilitate sealed access through the retracted opening,” as recited in amended independent claim 69. For at least this reason, claim 69 is allowable over Fadem and Hart.

Further, Applicant submits that the combination of Fadem and Hart fails to consider the claimed invention as a whole (see M.P.E.P. § 2141.02), in that neither Fadem nor Hart addresses multiple accessways through a retracted opening. For at least this reason, claim 69 is allowable over Fadem and Hart. Applicant respectfully cautions against the use of improper hindsight in rejecting the claims of this application.

For example, Applicant submits that substantial modification of a secondary reference to reject the claims evidences the improper use of hindsight reasoning.

Furthermore, even if, *arguendo*, dome 108 of Fadem could be modified to include hollow stems 18 of Hart or to include at least three sealable instrument openings 114, and Applicant does not agree that it can, neither Fadem nor Hart teaches that a sum of the diameters of at least two of hollow stems 18 or at least two sealable instrument openings 114 would be greater than a radius of dome 108. Thus, neither Fadem nor Hart discloses or suggests “a sum of the diameters of at least two of the accessways being greater than a radius of the sealing member,” as recited in amended independent claim 69.

The sum of the diameters of at least two of the accessways being greater than a radius of the sealing member, described in amended independent claim 69, provides advantages that are not disclosed or recognized in Fadem or Hart. For example, in the present application, making the sum of the diameters of accessways 136 and 137 greater than the radius of a sealing member 132, provides a sealing member 132 and accessways 136 and 137 that are sized in relation to one another to both accommodate the size of the instruments that travel through the passageways, and reduce the size of incision required for the surgical device. In contrast, a device with a dome 108 whose radius is many times larger than the diameter of a sealable instrument opening 114, such as the device shown in FIG. 4 of Fadem, provides extra room on dome 108 that is unnecessary for providing sealable instrument opening 114 or even multiple openings (which, according to page 5 of the Office Action, is taught by Hart). This extra room, while serving no apparent purpose, nevertheless necessitates the use of larger

components, such as the stiffener ring 90 coupled to dome 108, and a correspondingly sized incision. FIG. 3 of Fadem shows that the size of the incision “I” matches the size of the stiffener ring, and thus, as stiffener ring 90 is made larger, the incision “I” is made larger. Thus, the drawbacks associated with large components and incisions are present in Fadem as modified by Hart.

For all of the above-outline reasons, Applicant submits that the amendment to claim 69 overcomes the rejection under 35 U.S.C. § 103(a) based on Fadem and Hart. For at least this additional reason, claim 69 is allowable over Fadem and Hart.

III. New Claims

New claims 101-103 depend from amended independent claim 69 and are therefore allowable for at least the same reasons that claim 69 is allowable. In addition, these dependent claims recite unique combinations that are neither taught nor suggested by the cited art, and therefore are also separately patentable.

New independent claim 104 recites, *inter alia*, “a sealing member . . . including a dome shape when in use, and at least three accessways on the dome shape . . . axes of at least two of the accessways converging to a point, the point being located below a circumferential extent of the sealing member.” Support for claim 104 can be found in FIGS. 32-44 of Applicant’s drawings (see, e.g., FIG. 35). Neither Butler nor Hart teaches a dome shape. While Fadem teaches dome 108, Fadem does not teach at least three accessways on dome 108. See Fadem at FIG. 4. Even if, *arguendo*, dome 108 of Fadem could be modified to include hollow stems 18 of Hart or to include at least two sealable instrument openings 114 (as suggested on page 5 of the Office Action), and Applicant does not agree that it can, neither Fadem nor Hart teaches that

axes of two of hollow stems 18 or two sealable instrument openings 114 would converge to a point located below a circumferential extent of dome 108. Thus, claim 104 is allowable over the cited references. New claims 105-108 depend from claim 104 and are therefore allowable for at least the same reasons that claim 104 is allowable.

The sealing member including a dome shape when in use, with accessways on the dome shape, and axes of at least two of accessways converging to a point located below a circumferential extent of the sealing member, described in independent claim 104, provides numerous advantages that are not disclosed or recognized in Fadem or Hart. For example, in the present application, putting accessways 136 and 137 on the dome shape of sealing member 132, with axes of accessways 136 and 137 converging to a point located below a circumferential extent of sealing member 132, assists with triangulation of instruments by allowing distal portions of instruments inserted through accessways 136 and 137 to be naturally guided toward each another within the body cavity. Such triangulation assists in aligning multiple instruments within the incision. In addition, proximal portions of the instruments that remain outside of accessways 136 and 137 may be guided away from each other, creating more space for movement of the proximal portions of the instruments above sealing member 132. Further, the arrangement of accessways 136 and 137 on the dome shape, with their axes converging, may also help guide objects inserted through accessways 136 and 137 away from the edges of the wound opening, thus reducing contact with the edges of the wound opening, and making procedures less traumatic. These advantages are neither disclosed nor recognized by Fadem or Hart. For at least this additional reason, claims 104-108 are allowable over Fadem and Hart.

New independent claim 109 recites, *inter alia*, “a sealing member . . . including . . . at least three accessways . . . and a dome shape when in use, a proximal end of at least one of the accessways terminating at a proximal surface of the dome shape.” Support for claim 109 can be found in FIGS. 32-44 of Applicant’s drawings (see, e.g., FIG. 35). Neither Butler, Hart, nor Fadem teaches the above-recited features of claim 109. Butler fails to teach the accessways. See Butler at FIG. 25. While Fadem teaches dome 108 having sealable instrument opening 114, Fadem does not teach that the proximal end of sealable instrument opening 114 terminates at a proximal surface of dome 108. See Fadem at FIG. 4. Hart teaches multiple hollow stems 18, but hollow stems 18 suffer from the same deficiency as sealable instrument opening 114 of Fadem. Thus, claim 109 is allowable over the cited references. New claims 110-112 depend from claim 109 and are therefore allowable for at least the same reasons that claim 109 is allowable.

The sealing member including a dome shape when in use and accessways, described in independent claim 109, provides advantages, similar to those provided by independent claim 104 (see above), that are not disclosed or recognized in Fadem or Hart. For at least this additional reason, claims 109-112 are allowable over Fadem and Hart.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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